Program Announcement

Department of Defense Congressionally Directed Medical Research Programs

Breast Cancer Research Program

Predoctoral Traineeship Award

Funding Opportunity Number: W81XWH-09-BCRP-PREDOC

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I. FUNDING OPPORTUNITY DESCRIPTION

A. Program Objectives

The Breast Cancer Research Program (BCRP) was established in fiscal year 1992 (FY92) to promote innovative research focused on eradicating breast cancer. Appropriations for the BCRP from FY92 through FY08 totaled $2.2 billion. The FY09 appropriation is $150 million (M).

The BCRP challenges the scientific community to design innovative research that will foster new directions for, address neglected issues in, and bring new investigators to the field of breast cancer research. The BCRP focuses its funding on innovative projects that have the potential to make a significant impact on breast cancer, particularly those involving multidisciplinary and/or multi-institutional collaborations. The BCRP encourages risk-taking research; however, all projects must demonstrate solid judgment and rationale.

B. Award Description

The BCRP Predoctoral Traineeship Award was first offered in FY93. Since that time, 3,102 Predoctoral Traineeship Award applications have been received and 1,114 have been recommended for funding. The Predoctoral Traineeship Award supports the training of promising graduate students studying breast cancer under the guidance of a designated mentor to prepare them for successful careers in breast cancer research. Under this award mechanism, the predoctoral trainee is considered the Principal Investigator (PI) and, as such, should write the application with appropriate direction from the mentor. The mentor must clearly demonstrate a commitment to guiding the PI's research and training and must have a track record in breast cancer research. If the mentor is not an experienced breast cancer researcher, then a formal co-mentorship by an established breast cancer researcher is required.

Applications should emphasize:

- The PI's talent, potential, and *commitment to breast cancer research*,
- The mentor's qualifications and experience in breast cancer research,
- The level of the mentor's support of the PI's research and training,
- The strength of the training program in breast cancer research, and
- The institution's commitment to training future leaders in breast cancer research.

C. Eligibility

PIs must be graduate students (Ph.D. or M.D./Ph.D. program) under the guidance of a designated mentor who has experience (to include publications and funding) in breast cancer research. Applications submitted for "to be named" trainees are not allowed and will be administratively removed. Refer to the Application Instructions and General Information, Appendix 1, for general eligibility information.

D. Funding

- The maximum period of performance is 3 years.
- The maximum allowable funding for the entire period of performance is **$120,000** in direct costs.
- Up to $40,000 per year can be requested in direct costs; direct costs in excess of the stipend must be used as direct support for the PI and may not be used for research costs.
- Regardless of the period of performance proposed, you may not exceed the maximum direct cost. In addition to the direct costs, indirect costs may be proposed in accordance with your institution's negotiated rate agreement.
- The maximum indirect cost rate for training awards is 8%.
- The Predoctoral Traineeship Award should support the PI during dissertation research only.
- It is expected that the mentor will have adequate funding to support the PI's research.

Within the guidelines provided in the Application Instructions and General Information, funds can cover:

- Salary/stipend (PI only)
- Tuition
- Health insurance
- Training
- Workshops
- Travel to scientific/technical meetings

The Congressionally Directed Medical Research Programs (CDMRP) requires attendance at the triennially scheduled 3½-day Department of Defense BCRP Era of Hope meeting, which is held to disseminate the results of BCRP-sponsored research.

The CDMRP expects to allot $11M of the $150M FY09 BCRP appropriation to fund approximately 90 Predoctoral Traineeship Award applications, depending on the quality and number of applications received. Funding of applications received in response to this Program Announcement/Funding Opportunity is contingent on the availability of Federal funds for this program.

E. Award Administration

No change in PI is allowed for the Predoctoral Traineeship Award once the application has been submitted. Changes in institution will be allowed only at the discretion of the Grants Officer.

Refer to the Application Instructions and General Information, Appendix 5, for general award administration information.

II.   TIMELINE FOR SUBMISSION AND REVIEW

Proposal submission is a two-step process consisting of (1) pre-application submission and (2) application submission.

Pre-application Submission Deadline:	**February 25, 2009**
Confidential Letters of Recommendation:	**March 11, 2009**
Application Submission Deadline:	**March 11, 2009**
Scientific Peer Review:	**May 2009**
Programmatic Review:	**September 2009**

Awards will be made approximately 4 to 6 months after receiving a funding notification letter, but no later than September 30, 2010.

III.   SUBMISSION PROCESS

Proposal submission is a two-step process consisting of (1) a pre-application submission through the CDMRP eReceipt system (https://cdmrp.org/), and (2) an application submission through Grants.gov (http://www.grants.gov/).

PIs and organizations identified in the application submitted through Grants.gov should be the same as those identified in the pre-application. If there is a change in PI or organization after submission of the pre-application, the PI must contact the eReceipt help desk at help@cdmrp.org or 301-682-5507.

The Government reserves the right to reject duplicative applications submitted to different award mechanisms within the same program or to other CDMRP programs.

A.   Step 1 – Pre-Application Components and Submission

Pre-application submission is the required first step. The pre-application consists of the components discussed below. All pre-application components must be submitted electronically through the CDMRP eReceipt system by ***5:00 p.m. Eastern time on the deadline date***. Refer to the Application Instructions and General Information for detailed information.

- Proposal Information
- Proposal Contacts
- List of Individuals Providing Letters of Recommendation
- Collaborators and Conflicts of Interest (COI)
- Letter of Intent (LOI) Narrative

B. Step 2 – Application Components and Submission

Application submissions will not be accepted unless the pre-application process is completed by the pre-application deadline. Applications must be submitted electronically by the Authorized Organizational Representative (AOR) through Grants.gov (www.grants.gov).

Each application submission must include the completed application package of forms and attachments identified in www.grants.gov for the US Army Medical Research Acquisition Activity (USAMRAA) Program Announcement/Funding Opportunity. In addition to the specific instructions below, please refer to the Application Instructions and General Information for detailed requirements of each component.

The package includes:

1. **SF-424 (R&R) Application for Federal Assistance Form**

2. **Attachments Form**

   - Attachment 1: Project Narrative (six-page limit)

     The PI must describe the proposed research project, breast cancer research training program, and his/her career goals in the body of the application. Predoctoral Traineeship Award applications must be written by the trainee, while also showing evidence of appropriate direction from the mentor.

     Describe the proposed project using the following outline:

     o **PI's Career Goals:** Describe the PI's career goals and how the proposed training will promote the PI's career in breast cancer research or patient care. Discuss the PI's career plans after the completion of this award.

     o **Breast Cancer Training Program:** Describe the training plan, including a timeline, coursework, laboratory techniques, conferences, seminars, journal clubs, teaching responsibilities, and/or clinical responsibilities. Describe the mentor's background and experience in breast cancer research and how the mentor will assist the PI in developing his/her career. Explain how the training plan will advance the PI's development as a breast cancer researcher. Describe how the training plan is supported by the environment, including a description of ongoing breast cancer research at the institution. Include information on training or collaborations with other investigators.

     o **Research Project:** Describe the proposed project, including background, hypothesis/rationale/purpose, objectives, and methods. Discuss the relevance of this research to breast cancer.

- Attachment 2: Supporting Documentation
  - References Cited
  - Acronyms and Symbol Definitions
  - Facilities & Other Resources
  - Publications and/or Patent Abstracts (five-document limit)
  - List of Dissertation Committee Members
  - Transcripts
  - Letter of Formal Co-Mentorship Support (if applicable): If the mentor is not an experienced breast cancer researcher, then a formal co-mentorship by an established breast cancer researcher is required. Provide a signed letter from the Director of the graduate program that acknowledges the formal designation and role of the co-mentor for the PI's training program.
- Attachment 3: Technical Abstract (one-page limit)
- Attachment 4: Public Abstract (one-page limit)
- Attachment 5: Statement of Work (SOW; three-page limit)
- Attachment 6: Detailed Budget and Justification
- Attachment 7: Eligibility Statement

3. **Research & Related Senior/Key Person Profile (Expanded)**

- PI Biographical Sketch (four-page limit)
- PI Current/Pending Support
- Key Personnel Biographical Sketches (four-page limit each, include mentor's biographical sketch)
- Key Personnel Current/Pending Support (include mentor's current/pending support)

4. **Research & Related Project/Performance Site Location(s) Form**

Confidential Letters of Recommendation (three letters total, two pages each): In addition to the completed Grants.gov application package of forms and attachments, Predoctoral Traineeship Award applications also require the submission of **three** confidential letters of recommendation by the individuals [including the primary mentor(s)] designated during the pre-application process. All letters of recommendation must be submitted electronically through the CDMRP eReceipt system by *5:00 p.m. Eastern time on the deadline date*. The PI should monitor whether the letters have been received; however, the PI is not permitted or able to view these letters. If confidential letters of recommendation cannot be submitted by the individuals named in the pre-application, the PI should contact the CDMRP eReceipt help desk at help@cdmrp.org or 301-682-5507.

Confidential letter(s) of recommendation from the mentor(s): A letter must come from the PI's primary mentor, describing his/her commitment to the PI's training, career development, and mentorship. If the PI has a formal co-mentor, then that individual must also submit a letter of recommendation. Each mentor's letter of recommendation should describe:

- The PI's potential to become a breast cancer researcher;

- The mentor's commitment to the training, career development, and mentorship of the PI, including details of the mentor's proposed interactions with the PI during the PI's training;

- The mentor's experience in conducting breast cancer research, evidence of current funding in breast cancer, and record of training other predoctoral students;

- The relevance of the proposed research to training the PI in breast cancer;

- The PI's proposed research training program, including descriptions of the training environment, experience with laboratory techniques, conferences, and journal clubs, and how it will facilitate the PI's career development as a breast cancer researcher;

- The degree to which the PI participated in the idea development and application preparation, and the degree to which the PI will participate in the execution of the proposal if funded.

Additional confidential letters of recommendation: The remaining letter(s) should highlight the PI's potential for success in pursuing a career in breast cancer research. Specifically, each letter should include the writer's perspective on:

- The PI's qualifications, characteristics, and achievements,

- The PI's potential for productivity and desire for establishing a career in breast cancer research,

- The suitability of the mentor(s), research project, and training environment for providing the PI with a solid foundation in breast cancer research.

Refer to the Application Instructions and General Information, Section II.B., for additional information regarding submission of the letters of recommendation.

IV. INFORMATION FOR APPLICATION REVIEW

A. Application Review and Selection Overview

All applications are evaluated by scientists, clinicians, and consumer advocates using a two-tier review process. The first tier is a scientific peer review of applications against established criteria for determining scientific merit. The second tier is a programmatic review that compares submissions to each other and recommends proposals for funding based on scientific merit, the overall goals of the program, and the specific intent of the award mechanism. Additional information about the two-tier review process used by the CDMRP may be found at http://cdmrp.army.mil/fundingprocess.htm.

The peer review and programmatic review processes are conducted confidentially to maintain the integrity of the merit-based selection process. Each tier of review requires panelists to sign a non-disclosure statement attesting that application and evaluation information will not be disclosed outside the panel. Violations of the non-disclosure statement can result in the dissolving of a panel(s) and other corrective actions. Institutional personnel and PIs are prohibited from contacting persons involved in the application review process to gain protected evaluation information or to influence the evaluation process. Violations of these prohibitions will result in the administrative withdrawal of the institution's application. Violations by panelists or PIs that compromise the confidentiality of the peer review and programmatic review processes may also result in suspension or debarment of their employing institutions from Federal awards. Furthermore, it is a crime for Federal officials to disclose confidential information of one party to another third party (Title 18 United States Code 1905).

The Government reserves the right to review all applications based on one or more of the required attachments or supporting documentation (e.g., Innovation Statement or Impact Statement).

B. Review Criteria

1. Peer Review: All applications will be evaluated according to the following criteria, which are listed in decreasing order of importance.

- **Principal Investigator**
  - How the PI's achievements (as reflected by academic performance, awards, honors, and previous funding) indicate a potential for successful training in breast cancer research.
  - How the PI's stated career goals demonstrate a commitment to pursuing a career as a breast cancer researcher or clinician.
  - How the letters of recommendation support the PI's potential for productive breast cancer research.
  - Whether the PI meets the appropriate eligibility requirements.

- **Mentor**
  - How the mentor is appropriately trained and well suited to guide this research project, including the mentor's experience in breast cancer research.
  - Whether the mentor has current funding in breast cancer research.
  - How the mentor's training achievements, as reflected by his/her previous trainees' career achievements and areas of interest, indicate the potential for successful training of the PI in breast cancer research.
  - The appropriateness of the mentor's research experience, research program, committed resources, and level of effort for the proposed training program.
  - If the quality of the application suggests that the mentor provided appropriate guidance in its preparation.
  - Whether the mentor's letter of recommendation addresses each of the requested topics.

- **Training Program**
  - How the training focuses on breast cancer research.
  - How well the PI has outlined an individualized training program that augments his/her expertise.
  - How the training will prepare the PI for an independent career in breast cancer research.
  - The appropriateness of the scientific environment for the proposed training.
  - How the training requirements are adequately supported by the availability of facilities and resources (including collaborative arrangements).
  - The impact the training program will have on the PI's expertise in breast cancer research or patient care.
  - How the research project will train the PI to make valuable contributions to the study or treatment of breast cancer.

- **Research Strategy**
  - How well the hypotheses or objectives, aims, experimental design, methods, and analyses are developed.
  - Whether the research requirements are supported adequately by the scientific environment, necessary resources, and any collaborative arrangements proposed.
  - The appropriateness of the research project for the training plan and the level of training for the PI.
  - The appropriateness of the expertise of the dissertation committee members.

The following criteria will not be individually scored, but may impact the overall evaluation of the application:

- **Budget**
    - o How the budget is appropriate for the proposed research.

- **Application Presentation**
    - o How the writing and components of the application influenced the review.

2. Programmatic Review: The following criteria are used by programmatic reviewers to make funding recommendations that maintain the program's broad portfolio:

- Ratings and evaluations of the peer reviewers,

- Programmatic relevance,

- Program portfolio balance, and

- Adherence to the intent of the award mechanism.

Scientifically sound applications that best fulfill the above criteria and most effectively address the unique focus and goals of the program will be identified by Integration Panel (IP) members and recommended for funding to the Commanding General, USAMRMC. The highest scoring applications from the first tier of review are not automatically recommended for funding. All applications are carefully considered to ensure that the funds available are allocated to those proposals that best fulfill the goals, objectives, and areas of encouragement of the program.

V. ADMINISTRATIVE ACTIONS

After receipt of applications from Grants.gov, the following administrative actions may occur.

A. Rejection

The following will result in administrative rejection of the application:

- Project Narrative exceeds page limit.

- Project Narrative is missing.

- Budget is missing.

- Page size is larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm).

B. Modifications

- Pages exceeding the specified limits will be removed for all documents other than the Project Narrative.

- Documents not requested will be removed.

- *NEW for FY09:* Following the application deadline, you may be contacted by CDMRP via email with a request to provide certain missing supporting documents (excluding those listed in Section V.A, Rejection). The missing documents must be

provided within 48 hours of the date and time the email was sent. Otherwise, the application will be peer reviewed without the missing documents.

C.   Withdrawal

The following may result in administrative withdrawal of the application:

- FY09 IP member(s) is found to be involved in the pre-application or application processes including, but not limited to, concept design, application development, budget preparation, and the development of any supporting document. A list of the FY09 IP members may be found at http://cdmrp.army.mil/research.htm.

- Submission of the same research project to different award mechanisms within the same program or to other CDMRP programs.

- The application does not conform to this Program Announcement/Funding Opportunity description to an extent that precludes appropriate scientific peer and programmatic review.

- Direct costs as shown on the detailed budget form exceed the maximum allowed by the award mechanism.

- Inclusion of URLs, with the exception of links to published references.

D.   Withhold

Applications that appear to involve research misconduct will be administratively withheld from further consideration pending institutional investigation. The institution will be requested to provide the findings of the investigation to the USAMRAA Contracting/Grants Officer for a determination of the final disposition of the application.

VI.   CONTACT INFORMATION

A.   Program Announcement/Funding Opportunity, application format, or required documentation: To view all funding opportunities offered by the CDMRP, perform a Grants.gov basic search using the CFDA Number 12.420. Submit questions as early as possible. Response times will vary depending upon the volume of inquiries. Every effort will be made to answer questions within 5 working days.

Phone: 301-619-7079
Fax: 301-619-7792
Email: cdmrp.pa@amedd.army.mil

B.   eReceipt system: Questions related to pre-application components through the CDMRP eReceipt system should be directed to the eReceipt help desk, which is available Monday through Friday from 8:00 a.m. to 5:00 p.m. Eastern time.

Phone: 301-682-5507
Website: https://cdmrp.org
Email: help@cdmrp.org

C.   Grants.gov contacts: Questions related to application submission through the Grants.gov (http://www.grants.gov/) portal should be directed to the Grants.gov help desk. Deadlines for application submission are 11:59 p.m. Eastern time on the deadline date. Please note that the CDMRP help desk is unable to answer questions about Grants.gov submissions.

Phone: 800-518-4726, Monday through Friday, 7:00 a.m. to 9:00 p.m. Eastern time

Email: support@grants.gov

Grants.gov will notify PIs of changes made to this Program Announcement/Funding Opportunity and/or application package ONLY if the PI subscribes to the mailing list by clicking on the "send me change notification emails" link on the Opportunity Synopsis page for this announcement. If the PI does not subscribe and the application package is updated or changed, the original version of the application package may not be accepted.